

Date of Approval: April 10, 2024

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-777

Carprofen

Injectable Solution

Dogs

Carprofen is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

Sponsored by:

Felix Pharmaceutical Pvt. Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-777

B. Sponsor

Felix Pharmaceuticals Pvt. Ltd.
25-28 North Wall Quay
Dublin 1, Ireland

Drug Labeler Code: 086101

U.S. Agent Name and Address:

James H. Schafer, DVM
Schafer Veterinary Consultants, LLC
800 Helena Court
Fort Collins, CO 80524

C. Proprietary Name

Carprofen

D. Drug Product Established Name

carprofen

E. Pharmacological Category

Non-steroidal anti-inflammatory drug

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

50 mg/mL

H. How Supplied

20-mL, amber, glass, sterile, multi-dose vials

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The recommended dosage for subcutaneous administration to dogs is 2 mg/lb (4.4 mg/kg) of body weight daily. The total daily dose may be administered as either 2 mg/lb of body weight once daily or divided and administered as 1 mg/lb (2.2 mg/kg)

twice daily. For control of postoperative pain, administer approximately 2 hours before procedure.

K. Route of Administration

Subcutaneous injection

L. Species/Class

Dogs

M. Indication

Carprofen is indicated for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

N. Reference Listed New Animal Drug (RLNAD)

RIMADYL®; carprofen; NADA 141-199; Zoetis Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Felix Pharmaceuticals Pvt. Ltd., was granted a biowaiver for the generic product Carprofen injectable solution. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is RIMADYL® (carprofen) injectable solution, sponsored by Zoetis Inc., under NADA 141-199, and was approved for use in dogs on March 3, 2003.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Carprofen:

Keep out of reach of children. Not for human use. Consult a physician in cases of accidental human exposure.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Carprofen, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.